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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,580	11/21/2003	Frederic Beseme	105045.01	3397

25944 7590 08/24/2006

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EXAMINER	
MCGILLEM, LAURA L	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,580	BESEME ET AL.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,8-10,13-17,20 and 36-38* is/are pending in the application.

4a) Of the above claim(s) *21-23,30 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,8-10,13-17,20 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/446,024.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is noted that claims 1-2, 5-6, 8-10, 13-17, 20-23 have been amended, claims 3-4, 7, 11-12, 18-19, 24-29, 31-35 have been cancelled and claims 36-38 have been added in the amendment filed 6/9/2006. Added claim 36 is drawn to SEQ ID NO:7-9 which constitutes non-elected subject matter. Claim 36 will be withdrawn from consideration. Claims 1-2, 5-6, 8-10, 13-17, 20, and 37-38 are under examination.

Priority

The receipt of application FR 97/08815 in parent Application No. 09/446,024, now abandoned, is acknowledged. This Application receives benefit of priority to 07/07/1997.

Information Disclosure Statement

Applicant submits that the references cited therein were cited by or submitted to the Office in parent Application No. 09/446,024, filed December 16, 1999. Applicant submits that an initialed copy of a Form PTO-1449 listing this reference was attached to the January 31, 2002 Office Action in that application. Furthermore, as indicated in the IDS filed in the parent application on December 16, 1999, the references were cited in a counterpart foreign application and an English language version of the international search report was attached. Applicant submits that this
constitutes a concise explanation of the relevance of the European reference. MPEP 609.04(a)II1 For all of these reasons, the Applicants respectfully request that the

European patent reference be considered by the Examiner in the present application, and that such consideration be acknowledged.

The Foreign reference (EP 0 731 168) cited in the Information Disclosure Statement filed 1/12/2004 will be considered by the Examiner.

Election/Restrictions

Newly submitted claim 36 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: As discussed above, new claim 36 like presently withdrawn claim 30 are drawn to SEQ ID NOs:7-9, which are non-elected subject matter, and a search for these sequences would require an additional search of three additional, separate nucleotide sequences. As stated in the previous Office action, according to the policy for the examination of patent applications that claim large numbers of nucleotide sequences (see MPEP 2434), up to ten independent and distinct nucleotide sequences will be examined in a single application wherein "up to 10" can mean only one nucleotide sequence. The elected subject matter encompasses SEQ ID NO:11.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 36 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5-6, 8-10, 13-17, 20, and 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 -10 are vague and indefinite because they recite the phrase "highly stringent" conditions and the metes and bounds of highly stringent hybridization conditions are not clear.

This rejection is being maintained for reasons outlined in the Office Action mailed 12/19/2005 and those given below.

Applicants submit that there is no requirement that claims recite definitions for terms having meanings understood by those of ordinary skill in the art. Applicants submit that a cursory search of art relating to hybridization will reveal that the terms "high" and "low" stringency conditions respectively have a scope that is appreciated by skilled artisans. That is, a skilled artisan can readily determine whether hybridization is being conducted under highly stringent conditions.

Applicant's arguments filed 6/9/2006 have been fully considered but they are not persuasive. Hybridization stringency is dependent on multiple conditions such as temperature, salt content, etc. and the terms high and low stringency may be known in the art but they are subjective terms with subjective scopes. In the instant case, the specification does not provide enough information regarding what the Applicants intend

as "highly stringent" conditions so that the skilled artisan would know what hybridization conditions meet the limitations of the claims.

Claims 1 and 2 are vague and indefinite because they have been amended to recite the phrase "retroviral RNA molecule" and as the claims are written, it is not clear what characteristics the RNA must possess in order to be considered retroviral. Applicants submit that the phrase "retroviral RNA molecule" is well-understood by those of ordinary skill in the art, however the word "retroviral" preceding RNA appears to add a limitation to the RNA molecule. It is not clear whether an RNA molecule from a retrovirus that has been integrated into a genome meets the limitations of the claim. This is a NEW rejection necessitated by amendment.

Claims 8-10 are vague and indefinite because they have been amended to recite the phrase "derived specific amplification product thereof" and the metes and bounds of how the amplification product is derived is not clear. The specification discloses a definition that discloses cDNA derived from placenta RNA or cells expressing HERV-W (paragraph 0184), but it is not clear in what ways the cDNA can be derived from placental tissue or cells and still meet the limitations of the claims. Claims 5-6, 13-17, 20, and 37-38 are indefinite insofar as they are dependent on indefinite claim 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8, 13 and 15-17 are rejected under 35 U.S.C. 102(a) as being anticipated by NCBI report of Human BAC clone RG083M05 from chromosome 7q21-7q22 by Pauley, submitted 11/13/1996.

Applicants claim a probe for the detection of a nucleotide sequence selected from the group consisting of SEQ ID NO:11 and sequences that exhibit for every sequence of 100 contiguous monomers at least 70% homology, wherein the probe hybridizes under highly stringent conditions with said nucleotide sequence or any derived specific amplification thereof and wherein the probe contains at least six monomers.

The sequence of BAC clone RG083M05 comprises a sequence from nucleotide 35101 to nucleotide 37019 that displays a 98.9% local similarity to SEQ ID NO:11 from nucleotide 4802 to nucleotide 6721. Within that sequence, for example, the first six nucleotide sequences (nucleotide 35101 to nucleotide 35107) would anticipate a probe containing at least six monomers. Absent evidence to the contrary, a probe comprising at least six monomers from BAC clone RG083M05 would hybridize under highly stringent conditions with the claimed nucleotide sequence or any derived specific amplification thereof. Absent evidence to the contrary, the BAC clone would be double

stranded and therefore comprise the complementary sequence to the nucleotides 35101 to nucleotide 35107 which would contain at least six monomers of a complementary sequence of SEQ ID NO:11. As discussed above, the RG083M05 clone displays 98.9% identity to SEQ ID NO:11 over approximately 1918 nucleotides which would anticipate a probe having at least 70% homology or at least 90% homology with the complementary sequence of SEQ ID No:11.

Claims 8-10, 13 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al (U.S. Patent No. 5,708,157, filed 7/26/1996).

Jacobs et al teach a double stranded polynucleotide sequence known as SEQ ID NO:48 (see column 15, lines 65-67 and column 16, lines 1-10, for example). A portion of SEQ ID NO:48 from nucleotide 152 to nucleotide 341 displays a 100% local similarity to nucleotide 5390 to nucleotide 5579 of instant SEQ ID NO:11. Within that sequence, for example, the first six nucleotide sequences (nucleotide 152 to nucleotide 158) would anticipate a probe containing at least six monomers. Absent evidence to the contrary, a probe comprising at least six monomers from SEQ ID NO:48 as taught by Jacobs et al would hybridize under highly stringent conditions with said SEQ ID NO:11 nucleotide sequence or any derived specific amplification thereof. Since SEQ ID NO:48 is double stranded, it would therefore comprise the complementary sequence to the nucleotides 152 to nucleotide 158 which would contain at least six monomers of a complementary sequence of SEQ ID NO:11. As discussed above, the SEQ ID NO:48 displays 100% identity to SEQ ID NO:11 over approximately 189 nucleotides which would anticipate a

probe having at least 70% homology or at least 90% homology with the complementary sequence of SEQ ID NO:11. Jacobs et al teach that the sequences can incorporate labels or markers for various uses including use as probes and primers (see column 29, lines 30-60, for example) which reads on the claimed probe comprising a label or SEQ ID NO:48 as a primer that hybridizes under highly stringent conditions with SEQ ID NO:11 or any derived specific amplification product thereof.

Claims 8, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Jurka et al (J. Mol. Evol. 1992, Vol. 35, No. 4, pages 286-291).

Jurka et al teach prototypic sequences for human repetitive DNA, including a sequence from nucleotide 1923 to nucleotide 8523 with 95.7% local similarity to nucleotide sequence of SEQ ID NO:11 between nucleotide 606 to nucleotide 7255. Within that sequence, for example, the first six nucleotide sequences (nucleotide 1923 to nucleotide 1929) would anticipate a probe containing at least six monomers. Absent evidence to the contrary, a probe comprising at least six monomers from the sequence as taught by Jurka et al would hybridize under highly stringent conditions with said SEQ ID NO:11 nucleotide sequence or any derived specific amplification thereof. Absent evidence to the contrary, the sequence as taught by Jurka et al would be double stranded and therefore comprise the complementary sequence to the nucleotides 1923 to nucleotide 1929 which would contain at least six monomers of a complementary sequence of SEQ ID NO:11. As discussed above, the sequence as taught by Jurka et al displays 95.7% identity to SEQ ID NO:11 over approximately 6600 nucleotides which

would anticipate a probe having at least 70% homology or at least 90% homology with the complementary sequence of SEQ ID No:11.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD
8/21/2006

DANIEL M. SULLIVAN
PATENT EXAMINER